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09/937,295	11/29/2001	Mark Uden	078883-0134	9537

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EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1636

19

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/937,295

**Applicant(s)**

UDEN ET AL.

**Examiner**

Quang Nguyen, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 35,37-47 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34,36 and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10 and 17.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 1-49 are pending in the present application.

Applicant's election with traverse of Group I (claims 1-34 and 36) in the reply filed on 5/1/03 is acknowledged. Upon reconsideration, claim 48 of Group X is rejoined with claims of Group I. The traversal is on the ground(s) that Examiner has failed to demonstrate that a more serious examination burden exists for the search and examination of Group I together with Groups III, IV, VII, IX, X and XI. Group I relates to a retroviral vector comprising a functional splice donor site and a functional splice acceptor site, and obtained from a described pro-vector. Examination of such a retroviral vector will include consideration of the vector's production via reverse transcriptase from a provector (Group IV), the placement of functional introns (Group III), the resulting retroviral vector capable of differential expression of NOIs (Group XI), as well as consideration of lentiviral vector-derived components such as EIAV-derived plasmids and envelope plasmids (Group IX) and self-inactivating LTR retroviral components (Group X).

This is not found persuasive because none of the inventions of Groups III, IV, XI, and IX requires any retroviral vector or any pro-vector having the limitations of Group I. With respect to the invention of Group X, Applicants' arguments are moot since claim 48 has been rejoined with claims of Group I.

The requirement is still deemed proper and is therefore made FINAL.

Claims 35, 37-47 and 49 are withdrawn from further consideration because they are drawn to non-elected inventions.

Accordingly, claims 1-34, 36 and 48 are examined on the merits herein.

### ***Claim Objections***

Claim 4 is objected to because of the misspelled term "seconmd". Appropriate correction is required.

Claim 7 is objected to because of the presence of a period after the term "NOI" and after the term "element" in lines 1 and 3 of the claim. Appropriate correction is required.

Claim 32 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This is because there is no further limitation of the retroviral vector of claim 1 in claim 32.

### ***Information Disclosure Statement***

The IDS filed on 9/24/01 is not present in the present application. Should Applicants wish examiner to consider the references listed in the aforementioned IDS, copies of the references are requested.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-34 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, its dependent claims and claim 48 are vague and indefinite in that the metes and bounds of the term "derived from" are unclear. It is unclear the nature and number of steps required to obtain the claimed retroviral vector or self-inactivating retroviral vector. The term implied a number of different steps that may or may not result in a change in the functional characteristic of the retroviral vector or self-inactivating retroviral vector from the source that it is "derived from". It would be remedial to amend the claim language to use the term - - obtained from - -, which implies a more direct method of acquiring the retroviral vector of the present invention. Similar reasoning is applied for the term "derivable" in claims 27-28.

The term "near to" in claim 8 is a relative term which renders the claim indefinite. The term "near to" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear how many nucleotides from the 3' end that the first NS is considered to be or not to be near the 3' end. Therefore, the metes and bounds of the claim are not clearly determined.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and

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Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation "at or near to the 3' end of a retroviral pro-vector", and the claim also recites "preferably wherein the 3' end comprises a U3 region and an R region" and "preferably wherein the first NS is located between the U3 region and the R region" which is the narrower statement of the range/limitation.

Claim 33 provides for the use of a retroviral vector of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 33 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21, 27-32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Morgenstern et al. (Nucleic Acids Research 18:3587-3596, 1990).

Because of the term “derived from”, the claimed retroviral vector comprising a functional splice donor site (FSDS) and a functional splice acceptor site (FSAS) wherein the FSDS and the FSAS flank a first nucleotide sequence of interest (NOI) may or may not have any of the structural features of the retroviral pro-vector, therefore the following rejection is applied.

Morgenstern et al. disclosed the wild-type retroviral vector prZNSV(X) comprising a functional splice donor site and a functional splice acceptor site with the *hygro* gene in between said donor site and said acceptor site, and the *neo* gene that is placed downstream of the acceptor site (see Figure 2). The *Neo* gene is considered to be a “therapeutic agent” or a “diagnostic agent”, and the *hygro* gene is an agent conferring selectability. The retrovirus was packaged into infectious particles and they are used to infect cultured NIH 3T3 cells in which both *hygro*<sup>r</sup> and G418<sup>r</sup> were quantitated (legend of Figure 2). The retroviral vector of Morgenstern et al. is integrated because the retrovirus was isolated from stable Ψ-2 producer cells (legend of Figure 2).

Accordingly, the teachings of Morgenstern et al. meet all the limitation of the instant claims, and therefore the reference anticipates the instant claims.

Claims 1-4, 8-24, 27-34 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Leboulch et al. (WO 94/29470).

Because of the term "derived from", the claimed retroviral vector comprising a functional splice donor site (FSDS) and a functional splice acceptor site (FSAS) wherein the FSDS and the FSAS flank a first nucleotide sequence of interest (NOI) may or may not have any of the structural features of the retroviral pro-vector, therefore the following rejection is applied.

Leboulch et al. disclosed an LXS<sub>N</sub> retroviral vector for transducing Beta-globin gene and beta-locus control region derivatives for gene therapy, said retroviral vector comprises a beta-globin gene containing a promoter, three exons and two introns (with appropriate pairs of splice donor site and splice acceptor site) as well as the 5' splice site and the 3' splice site of the extended  $\Psi^+$  region (a functional intron), with a modified 3'LTR that has a 176 bp deletion to generate a self-inactivating vector (see Fig. 1, Fig. 5a-c, page 8 on the legend of Fig. 5a-c, and line 24 of page 13 continues to line 2 of page 16). Each exon of the beta-globin gene can be considered as a nucleotide of interest. The retrovirus of Leboulch et al. was packaged by producer cells into infectious particles which were used to infect NIH 3T3, MEL cells and bone marrow cells (page 19, section on stability of proviral transmission upon infection of cell-lines and murine bone marrow stem cells).



Accordingly, the teachings of Leboulch et al. meet all the limitation of the instant claims, and therefore the reference anticipates the instant claims.

Claims 1-21, 27-34 and 36 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. No. 09/508,516 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Claim 36 is provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 10/836,806 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35

U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21, 27-34 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5-6, 9-11, 14-17, 21-22, 47, 49-55, 57, 59-79 of copending Application No. 09/508,516. Although the conflicting claims are not identical, they are not patentably distinct from

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each other because the retroviral vector, the retroviral pro-vector and a method of producing the retroviral vector of the co-pending Application No. 09/508,516 anticipates the claimed genus in the application being examined and, therefore, a patent to the genus would, necessarily, extend the rights of the species or sub- should the genus issue as a patent after the species of sub-genus.

Please also note that because of the term "derived from", the claimed retroviral vector comprising a functional splice donor site (FSDS) and a functional splice acceptor site (FSAS) wherein the FSDS and the FSAS flank a first nucleotide sequence of interest (NOI) may or may not have any of the structural features of the retroviral pro-vector, and any nucleotide sequence can be a non-functional splice donor site (NFSDS) or a non-functional splice site (NFSS).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 36 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43 and 46 of copending Application No. 10/836,806. Although the conflicting claims are not identical, they are not patentably distinct from each other because the retroviral pro-vector of the co-pending Application No. 10/836,806 anticipates the claimed genus in the application being examined and, therefore, a patent to the genus would, necessarily, extend the rights of the species or sub- should the genus issue as a patent after the species of sub-genus. Additionally, please note that any nucleotide sequence can be a non-functional

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splice donor site (NFSDS) or a non-functional splice site (NFSS), and therefore the nucleotide sequence of interest in the retroviral provector of the co-pending application contains both NFSDS and NFSS.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusions**

#### ***No claims are allowed.***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.**

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.


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*Quang Nguyen, Ph.D.*

  
DAVID GUZO  
PRIMARY EXAMINER  
6/2/20